Statin prescribing in patients with metabolic dysfunction-associated steatohepatitis in the United States: An analysis of 3 real-world data sources

Yestle Kim, PharmD, MSc[1], David Lewandowski, MBA, BA[2], Taylor Marlin, MHI[2], Jessamine Winer-Jones, PhD[2], Lars Hegstrom, MD, MSHCT[3], Mark Brunk-Grady, MSc[4], Machaon Bonafede, PhD, MPH[2]

1. Madrigal Pharmaceuticals, Inc., West Conshohocken, PA, USA; 2. Veradigm, Chicago, IL, USA; 3. nference, Inc., Cambridge, MA, USA; 4. Carelon Research, Wilmington, DE, USA

BACKGROUND

- Metabolic dysfunction-associated steatohepatitis (MASH), also known as metabolic dysfunction-associated steatohepatitis, is a severe form of non-alcoholic fatty liver disease (NAFLD) or metabolic dysfunction-associated steatotic liver disease[1]
- The prevalence of MASH is estimated to be 1.5%-6.5% in the general population[2]
  - Dyslipidemia is one of the most common comorbidities in MASH, with an estimated prevalence of 60-70%[3-4]
  - As a common comorbidity, patients with dyslipidemia MASH have an increased risk of cardiovascular events[5]
- In the US, statins serve as the first-line treatment for dyslipidemia; however, statin use among MASH patients remains largely unknown

OBJECTIVE

- Given the paucity of evidence in the literature, the objective of this study was to examine real-world evidence of statin prescription and use in patients with MASH in the US

METHODS

Study population

- We identified adults (≥18 years) with a diagnosis of MASH from three US data sources: Carelon Research (Wilmington, DE, US), Veradigm (Chicago, IL, US), and nference (Cambridge, MA, US) (**Figure 1**)
- The ICD-10 diagnostic code K75.81 was used to identify patients with MASH in Carelon Research and Veradigm databases
- Patients with MASH were identified in nference using a comprehensive approach that included diagnostic codes, an enriched diagnostic query, and natural language processing, as well as a lab value ≥180 days from earliest diagnosis date and a biopsy

Figure 1. Study design
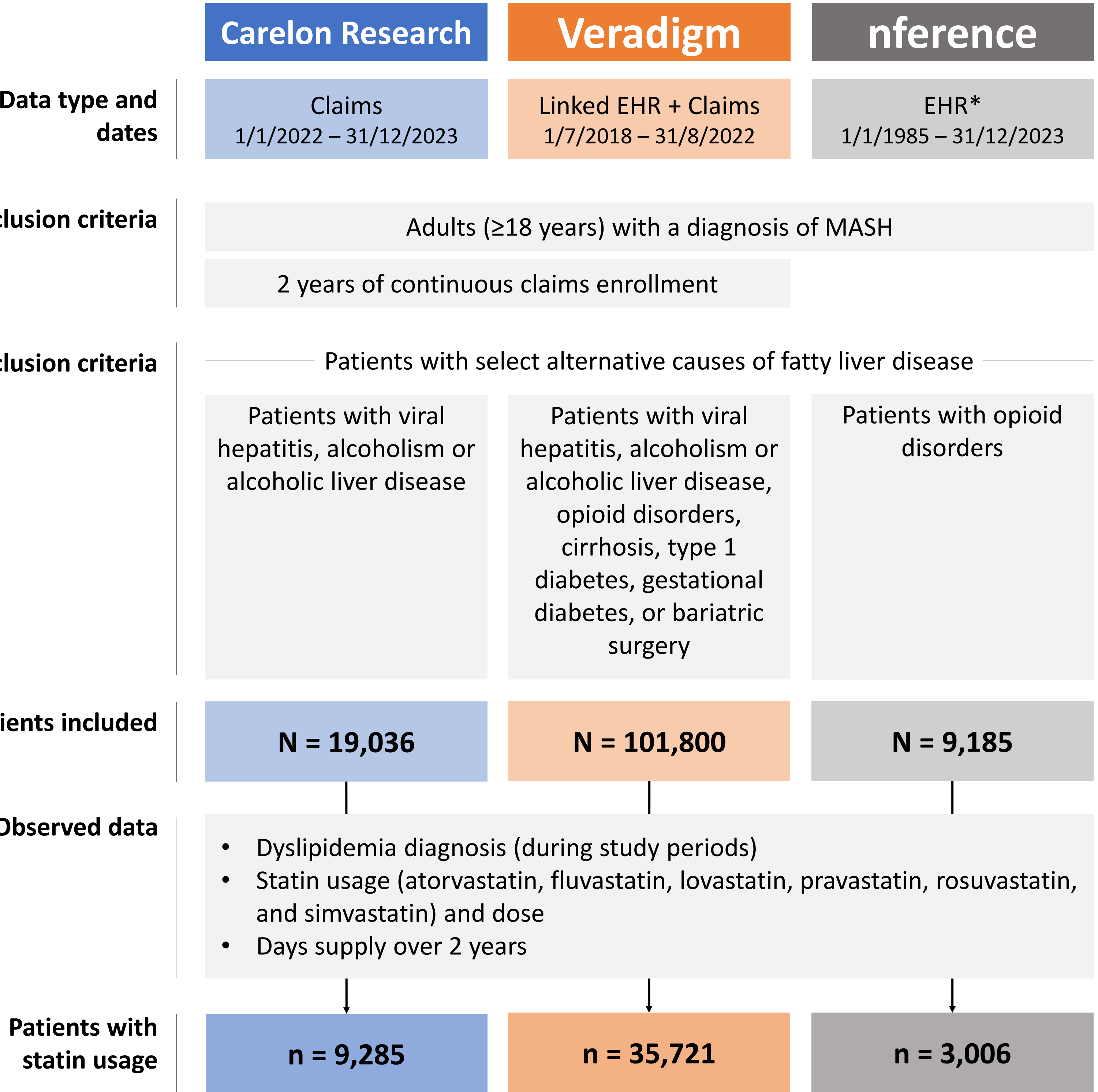
*Prescription counts include only the last order of statins, therefore, patient are only counted a single time

RESULTS

- The majority of patients with MASH in all 3 databases had a diagnosis of dyslipidemia during the study periods (**Table 1**)
- Statin use among patients with MASH was 48.8% (n = 9,285/19,036) in Carelon Research, 35.1% (n = 35,721/101,800) in Veradigm, and 32.7% (n = 3,006/9,186) in nference
- Among statin users, 53.4%-58.9% used atorvastatin, 25.0%-35.1% used rosuvastatin, 9.1%-11.7% used pravastatin, 8.5%-14.2% used simvastatin, and less than 3% used lovastatin or fluvastatin
- Across all adult MASH patients who met the selection criteria, few received the maximum recommended dose: 1.5%-2.5% received atorvastatin 80 mg, 0.2%-0.5% received pravastatin 80 mg, 0.7%-2.2% received rosuvastatin 40 mg, and 0.7%-1.6% received simvastatin 40 mg (0.0%-0.1% for simvastatin ≥80mg)
- Among the 4 most commonly used statins, median days' supply over a two-year period ranged from 160 – 630 days (mean 335 -560 days)

Table 1. Dyslipidemia diagnosis, and statin use, dosage, and days' supply over two years

	Carelon Research N = 19,036	Veradigm N = 101,800	nference N = 9,186
Dyslipidemia, n (%)	15,450 (81.2%)	76,287 (74.9%)	5,970 (65.0%)
Statin use, n (%)	9,285 (48.8%)	35,721 (35.1%)	3,006 (32.7%)
Statins of interest, n (% of statin users)			
Atorvastatin	4,957 (53.4%)	21,045 (58.9%)	1,607 (53.5%)
80mg	469 (5.1%)	2,169 (6.1%)	135 (4.5%)
High dose (≥40mg)	1,882 (20.3%)	8,753 (24.5%)	629 (20.9%)
Rosuvastatin	3,262 (35.1%)	9,183 (25.7%)	752 (25.0%)
40mg	422 (4.5%)	1,368 (3.8%)	63 (2.1%)
High dose (≥20mg)	1,262 (13.6%)	3,990 (11.2%)	250 (8.3%)
Pravastatin	846 (9.1%)	4,031 (11.3%)	353 (11.7%)
80mg	86 (0.9%)	377 (1.1%)	21 (0.7%)
Simvastatin	819 (8.8%)	5,061 (14.2%)	257 (8.5%)
40mg	275 (3.0%)	1,664 (4.7%)	61 (2.0%)
High dose (≥80mg)	22 (0.2%)	114 (0.3%)	3 (0.1%)
Lovastatin	134 (1.4%)	854 (2.4%)	21 (0.7%)
Fluvastatin	8 (0.1%)	30 (0.1%)	1 (0.0%)
High dose (≥80mg)	--	10 (0.0%)	0 (0.0%)
Unknown statin	--	--	15 (0.5%)
Days' supply of statins over 2 years			

	Mean	Median [25th, 75th]	Mean	Median [25th, 75th]	Mean*	Median [25th, 75th]*
Atorvastatin	511.9	600 [300, 720]	399	391 [175, 642]	481.4	360 [0, 800]
80mg	509.7	570 [330, 720]	349	330 [122, 570]	544.1	410 [0, 763]
High dose (≥40mg)	--	--	380	364 [150, 619]	532.2	390 [0, 810]
Rosuvastatin	476.7	540 [270, 720]	352	327 [120, 579]	513.3	360 [0, 810]
40mg	517.6	630 [270, 720]	343	304 [120, 560]	519.8	360 [0, 740]
High dose (≥20mg)	--	--	351	318 [127, 571]	521.9	360 [0, 810]
Pravastatin	453.1	510 [180, 720]	385	365 [145, 642]	402.6	160 [0, 720]
80mg	437.7	450 [203, 653]	381	360 [129, 652]	316.9	0 [0, 400]
Simvastatin	535.0	630 [360, 720]	415	433 [180, 675]	413.4	360 [0, 720]
40mg	559.8	630 [450, 720]	411	411 [180, 663]	434.9	360 [0, 720]
High dose (≥80mg)	--	--	335	297 [125, 563]	--	--

*Note: Prescribed supply in the nference database is reflected as the number of days supplied multiplied by the number of orders/refills. Prescription supplies that extend beyond the 2-year mark were unable to be removed from this count. Additionally, information regarding dosage changes was not able to be reflected in the time.

CONCLUSIONS

- Our study suggests that <50% of diagnosed MASH patients were on a statin (including high intensity treatments), and few received the maximum dosage
- Despite being the recommended first-line treatment for dyslipidemia in patients with MASH, additional data is needed to understand the low utilization rates of moderate-to-high intensity doses of statins

REFERENCES

1. Chalasani et al. Hepatology 2018; 67:328–357. **2.** Fishman et al. J Health Econ Outcomes Res. 2024; 11:32-43. **3.** Martin et al. Curr Atheroscler Rep 2022; 24:533-546. **4.** Xiao et al. J Clin Transl Hepatol 2022; 10;1042-1049. **5.** Zhang QQ, Lu LG. J Clin Transl Hepatol 2015; 3;78-84.